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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,770	03/06/2001	Todd M. Kinsella	A-68614-1/RMS/RMK	3911
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EXAMINER WESSENDORF, TERESA D				
ART UNIT		PAPER NUMBER		
1639				

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,770

Applicant(s)

KINSELLA, TODD M.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 59-87 is/are pending in the application.
- 4a) Of the above claim(s) 62 and 66-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Status of Claims***

Claims 1-58 have been cancelled.

Claims 59-87 are pending.

Claims 62 and 66-87 have been withdrawn from consideration as being drawn to non-elected invention. [Claims 68-81 are drawn to a library that have been restricted out in the restriction requirement of 1/28/03. Newly presented claims 82-87 are drawn to cells which have not been originally presented].

Claims 59-61 and 63-65 are under examination.

***Specification***

The disclosure is objected to because of the following informalities:

The specification, as amended, contains peptide sequences without any identifier (i.e., Seq. ID. No.). See e.g., SRGDGWS, page 7 of the instant amendment. Applicants are requested to check whether these sequences are also listed in the paper copy of the sequence listing and in the CRF.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61 and 63-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that a person of skill in the art reading the disclosure would clearly conclude that Applicants was in possession of the claimed subject matter. For instance, the specification specifically describes the claimed retroviral vectors on page 24, lines 1-2 and 7 and Figure 15A which discloses specific peptide of interest, retroviral vectors and the inteins.

In response, this is not controverted. However, what is controverted is the lack of description for any type of peptide of interest, the fusion polypeptide that undergoes a cyclization and the cyclic peptide containing any N and C-intein domain. As

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stated by applicants at page 16 of the instant REMARKS, ".....cyclization efficiency may be affected by the presence or absence of a given amino acid, the size of the peptide library, etc...." Considering that the cyclization is but only one of the numerous undefined variables or factors of the claimed invention. [Drafting the claim to the argued specific components of the retroviral can obviate this rejection].

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61 and 63-65 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

In view of the amendments to the claims the previous rejections have been overcome. However, the claims, as amended are rejected under this statute as follows:

It is not clear as to whether the peptide of interest is different from the cyclic peptide. Furthermore, it is not clear

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as to which part of the fusion polypeptide undergoes cyclization to form a cyclic peptide.

The rejection under 35 USC 102 no longer applies in view of applicants' arguments. However, newly amended claims are rejected under 103 as follows:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59-61 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott (PNAS) or Evans et al (The Jnl. of Biol. Chem.) in view of Nolan et al (6,153,380).

Scott discloses a bacterial vector comprising a DnaE split intein from *synechocystis* sp. PCC6803 to cyclize the *E. coli* enzyme dihydrofolate reductase and to produce a cyclic, eight-amino acid tyrosinase inhibitor in bacteria. See the Materials and methods at page 13638 up to page 13640. Scott further discloses the use of His-tag (reporter protein, as claimed). Evans et al basically discloses (at page 18359, Experimental

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Procedures up to page 18360) a similar bacterial vector with a fusion target of Ssp intein and Mxe Gyr which generate a cyclic peptide such as BBP, RGD and CDR. Scott or Evans does not disclose the use of retroviral as the vector in which the fusion polypeptide is inserted. However, Nolan discloses said retroviral containing a fusion polypeptide that cyclizes to produce a cyclic peptide. Nolan at col. 16, lines 25-34 that retroviruses are preferred for a number of reasons. First, their derivation is easy. Second, expression from retroviruses is long-term. Retroviruses therefore offer the best current compromise in terms of long-term expression, genomic flexibility, and stable integration, among other features. The main advantage of retroviruses is that their integration into the host genome allows for their stable transmission through cell division. This ensures that in cell types which undergo multiple independent maturation steps, such as hematopoietic cell progression, the retrovirus construct will remain resident and continue to express. It would have been obvious to one having ordinary skill in the art, at the time the invention was made to use a retroviral as a vector in the composition of either Scott or Evans as taught by Nolan. One having ordinary skill in the art would have been motivated to use a retroviral in a fusion polypeptide for the desirable properties taught by

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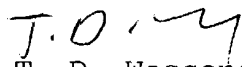
Nolan. Nolan discloses the used of the retroviral vector in a fusion polypeptide that results in a cyclic peptide.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
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tdw  
January 21, 2004